

## DEPARTMENT OF FISH AND GAME

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RE: CPG "Use of Medicated Feeds for Minor Species"

99D-2638

Section 615.115

To Whom it May Concern,

I have reviewed the draft CPG for extra-label use of **therapeutant in minor species**. My **concern** focuses on cultured **marine and freshwater fish and invertebrates**, species for which few therapeutants are approved. Due to the **paucity** of drugs that are legally **available** for use in cultured aquatic and marine species, the ability of qualified veterinarians to **prescribe** extra-label therapeutants is crucial for humane treatment of the animals and the **success of the aquaculture** industry. In addition, due to the size, number, **physiology** and stress susceptibility of **aquatic and marine animals**, administration of a therapeutant is typically only feasible as a oral application. This fact, in conjunction with the docket **99D-2638**, suggests that the act of prescribing a therapeutant by a licensed veterinarian **and/or** the application of a **therapeutant** by a **culturist** is an illegal act. That the **FDA** "**will not ordinarily consider** regulatory action against the veterinarian or animal producer provided all of the circumstances listed below exist" does not provide adequate **assurance** to the fish/invertebrate veterinarians or culturists who are acting in the best interest of the fish or invertebrate by treating a disease. This will result in a hesitance of veterinarians to **establish** relationships with and provide service to the fish/shellfish culture **industries which**, in turn, will result in a reduction in the ability of aquaculturists to maintain a high quality of animal husbandry during a disease epizootic. As the **shellfish** pathologist of the California Department of **Fish & Game** and a scientist who studies diseases of marine shellfish and works closely with the **aquaculture** industry, I firmly believe that an exception to the **current** regulatory status for extra-label prescription of therapeutants in feed for cultured marine and freshwater animals is warranted. My suggestion is that the aquaculture community and its veterinarians should be able to **use and prescribe o&label therapeutants in feed as long as the requirements in Section 615.115 are met**. Thus, this only necessitates a change of status for these species, not the proper requirements of **client/patient** relationship, withdrawal times, etc.

Please let me, **know** if you have any questions. I would appreciate a response to this letter.

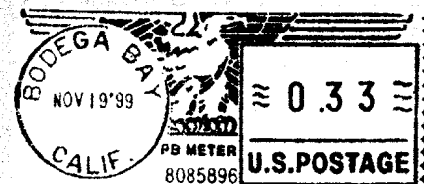
Sincerely,

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99D-2638

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